REMARKS

Regarding the Status of the Claims:

Claims 1 – 20 are pending.

Claims 13 – 20 have been rejoined with claims 1-12.

Claims 1 – 20 stand rejected.

Regarding the Objection to the Specification:

The Office action objects to the specification on the ground that it "does not provide proper antecedent basis for the various 'means for' limitations recited throughout claims 1 – 12."[1] As discussed below (with regard to Rejection I), there is no requirement that the phrase "means for" appear in the written description. The claims meet the applicable standards.

Regarding the Claim Rejections:

The Office action rejects:

I. claims 1 – 12 under 35 U.S.C §112, second paragraph;
II. claims 2 and 14 under 35 U.S.C §112, second paragraph;
III. claims 13 – 20 under 35 U.S.C §112, second paragraph; and
IV. claims 1 – 20 under 35 U.S.C §102(b) over US 5,972,295 to Hanawa et al. (hereinafter, "Hanawa").

Regarding Rejection I:

Applicants respectfully submit that the rejection of claims 1 – 12 under 35 U.S.C §112, second paragraph should be withdrawn. First, the Office action alleges, "the specification does not provide support for the 'means for' language used in the claims."[2]

[1] Page 2, lines of the 12 – 13 Office action mailed April 16, 2008.
[2] Page 2, line 22 – page 3, line 1 of the Office action mailed April 16, 2008.

Second, the Office action alleges, "the 'means for' is not modified by sufficient structure for achieving the specified function."[3]

The rejected claims recite the following "means for" elements:

1. means for loading one or more samples into one or more test vessels;
2. means for identifying tests to be performed on each of said one or more samples;
3. means for moving a plurality of test vessels to and from one or more resources of said plurality of resources;
4. means for setting one or more resource station levels; and
5. means for modifying said one or more resource saturation levels.

There is no requirement that the phrase "means for" appear in the written description. Rather, the test for determining whether a claim, employing "means plus function" terminology meets the definiteness requirement is whether

> "the corresponding structure (or material or acts) of a means (or step)-plus-function limitation [is] disclosed in the specification itself in a way that one skilled in the art will understand what structure (or material or acts) will perform the recited function."[4]

The rejected claims meet this standard.

First, one skilled in the art would understand what structure (or material or acts) will perform the recited "means for loading one or more samples into one or more test vessels" from the specification as filed. The specification explains, "[s]amples are loaded into the immunoassay analyzer either from the sample rack or by an operator ...."[5] Figure 10 illustrates a "means for loading one or more samples into one or more test vessels":

[3] Page 3, lines 6 – 7 of the Office action mailed April 16, 2008.
[4] MPEP §2181, citing *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1381, 53 USPQ2d 1225, 1230 (Fed. Cir. 1999).
[5] Page 15, lines 20 – 21 of the specification.

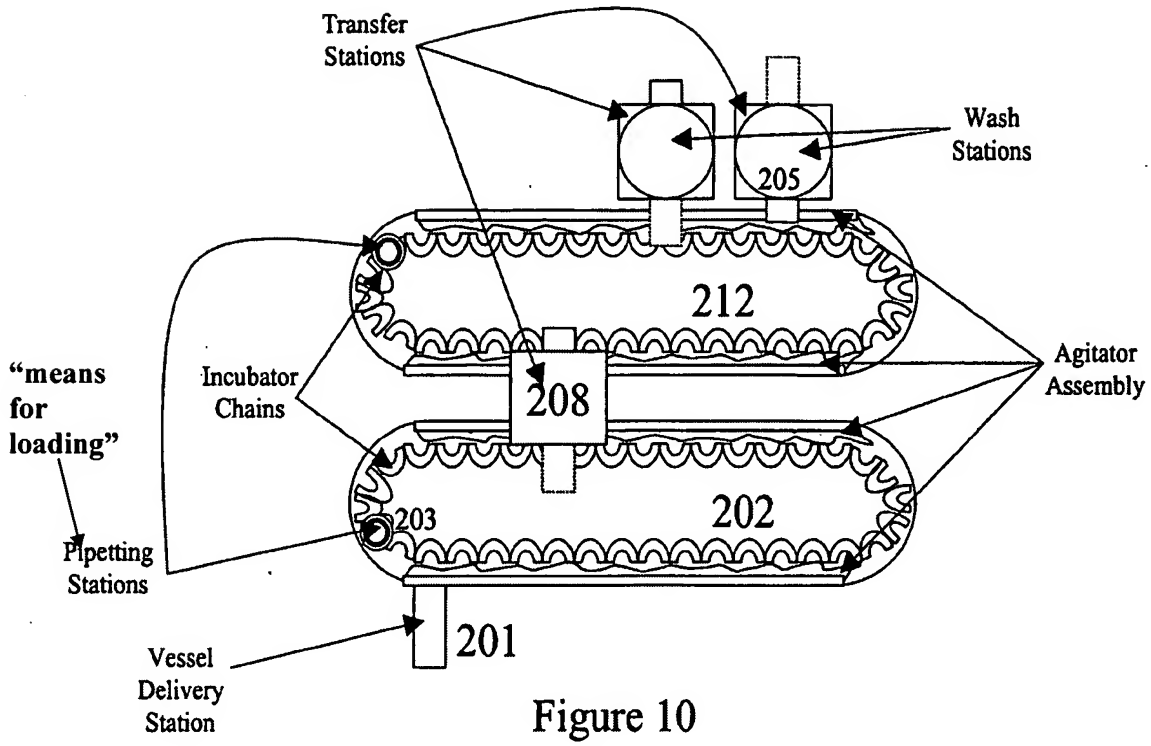

Figure 10

Making reference to Figure 10, the specification explains, "[t]he test vessel is moved to a pipetting station 203 where liquid is added. The liquid that is added may include biological sample (e.g., blood, plasma, urine, etc.), or diluted biological sample, or liquid reagent."[6]

Second, one skilled in the art would understand what structure (or material or acts) will perform the recited "means for identifying tests to be performed on each of said one or more samples." The specification explains, "[t]he selection of bead and reagent for each sample is managed by the controller subsystem 101 based on the type of test to be performed on each sample. These subsystems include identification capabilities such as bar code readers or RF tag readers that read the identification information on the reagent containers, bead containers and test vessels to ensure that correct components are added to each test vessel for testing."[7] The specification also states, "[a] bar code reader, RF tag, or other means for identifying the samples can be used to associate the desired

[6] Page 21, lines 20 – 23 of the specification.
[7] Page 7, lines 9 – 15 of the specification.

tests with the specific samples to be tested."[8]

Third, one skilled in the art would understand what structure (or material or acts) will perform the recited "means for moving a plurality of test vessels to and from one or more resources of said plurality of resources." The specification explains, "[t]he pathways for moving from one step to another are represented by arrows, and will typically coincide with physical movement of a sample tube from one section of the instrument to another (e.g. from a pipetting station to a transfer or wash station) by means of a transport device such as an incubator belt."[9]

Fourth, one skilled in the art would understand what structure (or material or acts) will perform the recited "means for setting one or more resource station levels." The specification explins, "[t]he test data, such as test types, test paths, resource utilization and other related information is entered into the controller via the user interface 24 using anyone of several input devices such as bar code reader, keyboard, mouse, etc."[10] Page 18, line 16 – page 19, line 16 of the specification provides even more detail.

Fifth, one skilled in the art would understand what structure (or material or acts) will perform the recited "means for modifying said one or more resource saturation levels." The specification provides ample explanation on page 7, lines 28 – 31 and page 18, line 16 – page 19, line 16. In view of the foregoing, withdrawal of this ground of rejection is requested.

Regarding Rejection II:

Applicants respectfully submit that the rejection of claims 2 and 14 under 35 U.S.C §112, second paragraph should be withdrawn. Claim 2 requires the controller to determine an optimized launch of test sequence for each sample based on any samples currently under test and any samples yet to be tested, said launch of test sequence controlling a time and order for tests to be launched.

The Office action alleges, "[i]t is unclear what constitutes an 'optimized' launch of test sequence."[11] The Office action also alleges, "the phrase 'a launch of test

[8] Page 3, line 30 – page 4, line 1 of the specification.
[9] Page 10, lines 11 – 15 of the specification.
[10] Page 7, lines 28 – 31 of the specification.
[11] Page 3, lines 21 – 22 of the Office action mailed April 16, 2008.

sequence' is unclear."[12] Again, it is axiomatic that claims must be interpreted not in a vacuum, but in light of the specification. The specification explains, "[t]he dynamic controller will calculate test sequences for each of the samples based on resource and timing requirements and will launch the tests in an optimized sequence. Furthermore, the dynamic controller of the present invention permits accessing the samples in a randomized fashion, as opposed to a serial, one after the other, fashion. This allows for a controller to manage the varying time periods between entering samples into the analyzer instrument for testing and processing the samples through the selected assays. In this way, the time durations for the various types of tests being performed can be optimized."[13] Thus, one skilled in the art reading the claim in light of the specification would understand what would constitute an optimized launch of test sequence as claimed.

Second, the Office action alleges, "it is unclear how the controller determines a launch of test sequence for a sample that is already under test, and how a time and order for tests to be launched is achieved with samples that are already under test."[14] In response, it is explained that a launch of test sequence is determined even for samples that are already under test. Typically, such a sample would remain at "the front of the line." However, in some circumstances the controller may halt a test that is underway, and assign it an optimized launch of test sequence that places the sample at "the back of the line." The specification explains that in preferred embodiments, "[i]n order to allow higher priority tests to be launched without halting samples currently under test, some resources must be available at all times to introduce the high priority tests into the instrument."[15] In view of the foregoing, withdrawal of this ground of rejection is requested.

Regarding Rejection III:

Applicants respectfully submit that the rejection of claims 13 – 20 under 35 U.S.C §112, second paragraph also should be withdrawn. The Office action alleges, "[i]t is unclear what is meant by, 'moving each of said plurality of test vessels along its

[12] Page 4, line 8 of the Office action mailed April 16, 2008.
[13] Page 4, lines 1 – 13 of the specification.
[14] Page 4, lines 3 – 5 of the Office action mailed April 16, 2008.
[15] Page 18, lines 25 – 28 of the specification.

respective path determined in said using a computer controller to determine step.'" The penultimate step recited in claim 13 is "using a computer controller to determine a path for each test vessel." The final step is "moving each of said plurality of test vessels along its respective path determined in said using a computer controller to determine step."

Applicants respectfully note that "[t]he examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available."[16] Moreover, "[s]ome latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement."[17] In view of the foregoing, withdrawal of this ground of rejection is requested.

Regarding Rejection IV:

Applicants respectfully submit that the rejection of claims 1 – 20 under 35 U.S.C §102(b) over Hanawa should be withdrawn. Anticipation only can be established by a single prior art reference which discloses each and every element of the claimed invention.[18] "The identical invention must be shown in as complete detail as is contained in the patent claim."[19]

First, Hanawa does not show a means for identifying tests to be performed. Instead, the reference shows "a bar-code reader **5** as an identifying apparatus for identifying a destination of [a] sample rack...."[20] This bar-code reader merely determines "whether the sample rack carried is a sample rack which needs not to be reexamined or a general sample rack which may need to be reexamined."[21] The bar-code

[16] MPEP §2173.02.
[17] MPEP §2173.02.
[18] *See, RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444 (Fed. Cir. 1984).
[19] *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).
[20] Column 4, lines 45 – 46 of US 5,972,295.
[21] Column 3, lines 18 – 22 of US 5,972,295.

reader does not identify tests to be performed. Thus, Hanawa does not anticipate the claimed invention.

Second, Hanawa does not show a plurality of resources, each of said plurality of resources for performing a specified function on a test vessel. As stated succinctly in the claims, Hanawa merely provides a single "analyzing unit for testing an analysis item of a sample sampled from a sample container contained in the sample rack...."[22] Thus, Hanawa does not anticipate the claimed invention.

Third, Hanawa does not show that each of the tests is to be performed in a test vessel. Hanawa removes the sample from the sample container for testing (See: Column 5, lines 29 – 41 of US 5,972,295). The Office action states, "the test vessels are not positively recited elements in the claims, and thereby the recitation to the tests being performed in a test vessel is a recitation that is drawn to an intended use that is not afforded patentable weight."[23] In response, applicants respectfully urge that the "claims must be considered as a whole."[24] MPEP §2106 explains, "when evaluating the scope of a claim, every limitation in the claim must be considered. USPTO personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered." Each element of the immunoassay analyzers of claims 1 – 12, and each step of the automated methods of claims 13 – 20 operates in conjunction with one or more test vessels. The invention as a whole clearly requires each test to be performed in a test vessel. It is improper to dissect this requirement out of the claims.

Fourth, Hanawa does not show a computer controller which tracks the location of each test vessel. Hanawa does not utilize test vessels. Hanawa uses sample containers, from which the sample is removed for testing. Clearly, Hanawa does not show a computer controller, which tracks the location of test vessels, since no test vessels are employed.

The Office action asserts, "Hanawa discloses a computer controller and thereby such controller is capable of such functionalities."[25] Applicants respectfully reassert that

[22] Column 12, lines 21 – 23 of US 5,972,295.
[23] Page 7, line 21 – page 8, line 2 of the Office action mailed April 16, 2008.
[24] *Diamond v. Diehr*, 450 U.S. 175, 188-89, 209 USPQ 1, 9 (1981).
[25] Page 8, lines 11 – 12 of the Office action mailed April 16, 2008.

in order to support an anticipation rejection, "[t]he identical invention must be shown in as complete detail as is contained in the patent claim."[26] Hanawa does not show a computer controller, which tracks the location of test vessels. Thus, Hanawa does not anticipate the claimed invention.

Additionally, it seems worth noting that Hanawa does not even track the location of the sample racks from which samples are removed for testing. Instead, the sample racks are processed in a first-in-first-out manner. The reference is unconcerned with the location of each sample within the analyzing apparatus, and merely determines at the fixed location of the bar-code reader whether a given sample needs to be reexamined.

Finally, Hanawa does not show a computer controller which determines a path for each test vessel between each resource based on the test identified for said test vessel by said means for identifying and the tests identified and location for all other test vessels of said plurality of test vessels. Hanawa does not show test vessels, does not show a plurality of resources, and does not identify a test for each test vessel, thus the reference clearly does not determine a path for each test vessel between each resource and does not determine a path based on the test identified for each vessel, and the locations of all vessels. Instead, Hanawa merely determines whether each sample rack should be directed to the rack collecting unit **23** or the standby unit **40** based on whether the rack is likely to need to be reexamined.

[26] *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Conclusion:

The present application is respectfully submitted to be in condition for allowance. Applicants request favorable action in this matter. In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner is welcome to contact the undersigned by phone to further the discussion.

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